DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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January 26, 2015

Chin Bone Technique Corporation
Mr. Cheng-Kung Cheng
Number 165, Section 2, Xi'an Street, Beitou District
Taipei, Taiwan 11274
CHINA

Re: K142655
Trade/Device Name: CB PROT II Posterior Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNH, MNI
Dated: December 26, 2014
Received: December 31, 2014

Dear Mr. Cheng:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142655

Device Name
CB PROT II Posterior Spinal System

Indications for Use *(Describe)*
The CB PROT II Posterior Spinal System is intended to provide immobilization and stabilization for posterior, non-cervical, pedicle fixation of the thoracic, lumbar and sacral spinal elements (T1-S1) as an adjunct to fusion for the following indications:

- Trauma (i.e. fracture or dislocation).
- Spinal stenosis.
- Vertebral tumors.
- Pseudoarthrosis and failed previous fusion in skeletally mature patients.
- Scoliosis, kyphosis and lordosis, and severe spondylolisthesis (grade 3 or 4) of the T1-S1 vertebra.

The system is intended to be used with autograft or allograft to facilitate fusion.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY

This summary regarding 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21CFR 807.92(c).

Submitter Information: Chin Bone Technique Corp.
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Date prepared: December 26, 2014

Trade Name: CB PROT II Posterior Spinal System

Device Class: Class II

Produce Code: MNI, MNH

Common Name: Pedicle screw system

Classification Name: Pedicle screw spinal system

Regulation Number: 21 CFR 888.3070

Predicate Devices: SmartLoc™ spinal fixation system (K111883)

Material: The CB PROT II Posterior Spinal System components are manufactured from medical grade titanium alloy (Ti6Al4V) that meets ASTM F136 & ISO 5832-3.

Device Description:

The CB PROT II Posterior Spinal System consists of non-sterile rods, monoaxial and polyaxial pedicle screws. The thoraco-lumbar rods are available in a variety of lengths (one diameter). Screws are available in various lengths and diameters according to practical requirements.

Indications for Use:

The CB PROT II Posterior Spinal System is intended to provide immobilization and stabilization for posterior, non-cervical, pedicle fixation of the thoracic, lumbar and sacral spinal elements (T1-S1) as an adjunct to fusion for the following indications:

- Trauma (i.e. fracture or dislocation).
- Spinal stenosis.
- Vertebral tumors.
- Pseudoarthrosis and failed previous fusion in skeletally mature patients.
- Scoliosis, kyphosis and lordosis, and severe spondylolisthesis (grade 3 or 4) of the T1-S1 vertebra.

The system is intended to be used with autograft or allograft to facilitate fusion.

Performance Data:

Mechanical testing including static/dynamic axial compression bending test and static torsion test were conducted referring to ASTM F1717 to demonstrate substantial equivalence to the predicate system. The results represented that the CB PROT II Posterior Spinal System performs as well as or better than the predicate device.

Conclusion of Substantial Equivalence:

The CB PROT II Posterior Spinal System has been demonstrated to be substantially equivalent to predicate system with respect to technical characteristics, performance, and intended use. The information provided within this premarket notification supports substantial equivalence of the subject device to the predicate device.